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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/729,658 | 12/04/2000 | Jonathan Zonana | 6005-55924 | 3101 |

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| EXAMINER | |
|---|---|
| MARVICH, MARIA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1636 | |

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/729,658 | ZONANA ET AL. | |
| | Examiner | Art Unit | |
| | Maria B Marvich, PhD | 1636 | |

*-- Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-58 are pending in this application.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 8-12 and 41-42, drawn to a method of increasing hair follicle development, tooth development or sweat gland development comprising administration of an EDA1-II nucleic acid to increase EDA1-II activity in the tissue, classified in class 514, subclass 44 and class 435 subclass 455.

II. Claims 1-6, 22-26 and 41-42, drawn to a method of increasing hair follicle development, tooth development or sweat gland development comprising administration of an EDA1-II protein to increase EDA1-II activity in the tissue, classified in class 514, subclass 2 and class 530 subclass 350.

III. Claims 1-6, and 41-42, drawn to a method of increasing hair follicle development, tooth development or sweat gland development comprising increasing EDA1-II expression in the tissue to increase EDA1-II activity in the tissue, classified in class 435, subclass 375.

IV. Claims 1-7 and 41-42, drawn to a method of increasing hair follicle development, tooth development or sweat gland development comprising increasing EDA1-II sensitivity to increase EDA1-II activity in the tissue, classified in class 435, subclass 375.

V. Claims 1-5, 14, 27-31 and 41-42, drawn to a method of increasing hair follicle development, tooth development or sweat gland development comprising administration of a Dl or dl protein to increase EDA1-II activity in the tissue, classified in class 514, subclass 2 and class 530 subclass 350.

VI. Claims 1-5, 14, 16-21 and 41-42, drawn to a method of increasing hair follicle development, tooth development or sweat gland development comprising increasing DL or dl expression to increase EDA1-II activity in the tissue, classified in class 435, subclass 375.

VII. Claims 1-5, 14-15 and 41-42, drawn to a method of increasing hair follicle development, tooth development or sweat gland development comprising increasing DL or dl sensitivity to increase EDA1-II activity in the tissue, classified in class 435, subclass 375.

VIII. Claims 1-5, 32-33 and 41-42, drawn to a method of increasing hair follicle development, tooth development or sweat gland development comprising administration of a Dl or dl binding agent to increase EDA1-II activity in the tissue, classified in class 435, subclass 334.

IX. Claims 1, 34-37 and 43, drawn to a method of decreasing hair follicle development, tooth development or sweat gland development comprising administration of an EDA1-II antisense molecule to decrease EDA1-II expression or sensitivity in the tissue, classified in class 514, subclass 44.

X. Claims 1, 34-39 and 43, drawn to a method of decreasing hair follicle development, tooth development or sweat gland development comprising

administration of a specific binding agent to decrease EDA1-II expression or sensitivity in the tissue, classified in class 435, subclass 375.

XI. Claims 1, 34-37, and 43 drawn to a method of decreasing hair follicle development, tooth development or sweat gland development comprising administration of an EDA1-II antagonist to decrease EDA1-II expression or sensitivity in the tissue, classified in class 435, subclass 375.

XII. Claims 1, 34-36, 40 and 43, drawn to a method of decreasing hair follicle development, tooth development or sweat gland development comprising administration of a DL or dl antagonist, classified in class 435, subclass 375.

XIII. Claims 44-45, drawn to a composition comprised of an EDA1-II polypeptide encoded by SEQ ID 2 or 17 or 19, classified in class 530, subclasses 351 and 412.

XIV. Claims 46, drawn to a composition comprising an EDA1-II antagonist classified in class 424, subclass 198.1.

XV. Claim 46 drawn to a composition comprising a dl or DL antagonist classified in class 435, subclass 143.1.

XVI. Claim 46, drawn to a composition comprising a nucleic acid consisting of amino acids 1-183 of the DL or dl receptor, classified in class 435, subclass 69.1.

XVII. Claim 46, drawn to a composition comprising an EDA1-II specific binding agent, classified in class 536, subclass 388.22.

XVIII. Claim 46, drawn to a composition comprising a DL or dl specific binding agent, classified in class 536, subclass 388.22.

XIX. Claims 47-48, drawn to a composition comprised of an EDA1-II polypeptide encoded by SEQ ID 2 or 17 or 19 and an additional compound which increases or decreases hair follicle development, tooth development, or sweat gland development, classified in class 530, subclass 350.

XX. Claim 49-50, drawn to an EDA1-II antisense oligonucleotides, classified in class, subclass 536, subclass 22.1.

XXI. Claim 51-58, drawn to a method for screening for compounds that bind to DL or dl receptor and increase hair follicle development, tooth development or sweat gland development classified in class 435, subclass 7.1.

XXII. Claim 51-58, drawn to a method for screening for compounds that bind to DL or dl receptor and decrease hair follicle development, tooth development or sweat gland development classified in class 435, 435, subclass 7.1.

The inventions are distinct each from the other because of the following reasons:

The methods of Groups I-XII and XXI-XXII are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Group I comprise steps that are not required for or are present in the methods of Groups II-XII and XXI-XXII: administration of EDA1-II nucleic acid to target tissue. The methods of Group II comprise steps that are not required for or are present in the methods of Groups I and III-XII and XXI-XXII: administration of EDA1-II protein to target tissue. The methods of Group III comprise steps that are not required for or are present in the methods of Groups I-II and IV-XII and XXI-XXII: increasing EDA1-II expression in the target tissue. The methods of Group IV

comprise steps that are not required for or are present in the methods of Groups I-III and V-XII and XXI-XXII: increase EDA1-II sensitivity in the target tissue. The methods of Group V comprise steps that are not required for or are present in the methods of Groups I-IV and VI-XII and XXI-XXII: administration of DL or dl protein to target tissue. The methods of Group VI comprise steps that are not required for or are present in the methods of Groups I and I-V and VII-XII and XXI-XXII: increase DL or dl expression in the target tissue. The methods of Group VII comprise steps that are not required for or are present in the methods of Groups I-VI and VIII-XIII and XXI-XXII: increase DL or dl sensitivity in the target tissue. The methods of Group VIII comprise steps that are not required for or are present in the methods of Groups I-VII and IX-XII and XXI-XXII: administration of a DL or dl binding agent. The methods of Group IX comprise steps that are not required for or are present in the methods of Groups I-VIII and XXI-XXII: administration of an EDA1-II antisense. The methods of Group X comprise steps that are not required for or are present in the methods of Groups I-IX and XI-XII and XXI-XXII: administration of an EDA1-II specific binding agent. The methods of Group XI comprise steps that are not required for or are present in the methods of Groups I- X and XII and XXI-XXII: administration of an EDA1-II antagonist. The methods of Group XII comprise steps that are not required for or are present in the methods of Groups I-XI and XXI-XXII: administration of a DL or dl antagonist. The methods of Group XXI comprise steps that are not required for or are present in the methods of Groups I-XII and XXII: assay for test compounds that increase hair follicle, tooth or sweat gland development. The methods of Group XII comprise steps that are not required for or are present in the methods of Groups I-XII and XXI: assay for test compounds that decrease hair follicle, tooth or sweat gland development.

The outcome of each of Groups I-VIII will differ based upon the method employed to increase or decrease EDA1-II activity. For example, the effect of Group I, administration of DEA1-II nucleic acid, is a target tissue is transformed and expresses the nucleic acid. The effect of Group II, administration of an EDA1-II protein, is a target tissue that contains recombinant EDA1-that can immediately functions to bind receptor. The outcome of Group XXI, identification of a test compound that increases hair follicle, tooth or sweat gland development differs from that of Group I-XII and XXII. The outcome of Group XXII, identification of a test compound that decreases hair follicle, tooth or sweat gland development differs from that of Group I-XII and XXI. Thus the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different and distinct groups are capable of supporting separate patents.

The EDA1-II polypeptide of Group XIII and XIX and the methods of Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05 (h)). In the instant invention, the polypeptide can be used to generate antibodies to EDA1-II.

The EDA1-II antagonist of Group XIV and the methods of Group XI are related as product and process of use. The inventions can be shown to be distinct as the EDA1-II antagonist can be used in a receptor-binding assay. Similarly, the DL or dl antagonist of Group XV and the methods of Group XII are related as product and process of use. The inventions can be shown to be distinct as the Dl or dl antagonist can be used in a receptor-binding assay. The

EDA1-II specific binding agent of Group XVII and the method of Group X are related as product and process of use. The inventions can be shown to be distinct as the EDA1-II specific binding agent can be used to increase hair follicle, sweat gland or tooth development. The DL or dl specific binding agent of Group XVIII and the method of Group X are related as product and process of use. The inventions can be shown to be distinct as the Dl or dl specific binding agent can be used to increase hair follicle, sweat gland or tooth development. The EDA1-II antisense oligonucleotides of Group XX and the methods of Group IX are related as product and process of use. The inventions can be shown to be distinct as the antisense oligonucleotides can be used as primers in a PCR reaction.

The EDA1-II polypeptide of Group XIII, the EDA1-II antagonist of Group XIV, the dl or DL antagonist of Group XV, the EDA1-II nucleic acid of Group XVI, the EDA1-II specific binding agent of Group XVII, the Dl or dl specific binding agent of Group XVIII, the composition of Group XIX comprised of an EDA1-II polypeptide and an additional compound and the antisense oligonucleotides of Group XX are directed to products that are distinct both physically and functionally from one another and therefore have different modes of operation, different functions and different effects. Therefore, the inventions of the different groups are capable of supporting separate patents.

The invention reads on 3 patentably distinct cDNA sequences comprising one of SEQ ID numbers 1, 12 and 18 and 3 patentably distinct amino acid sequence comprising SEQ ID numbers 2, 17 and 19. Each sequence is patentably distinct because they are unrelated sequences. It has been decided that, due to the high burden placed on the Office to search sequences, ONE sequence constitutes a reasonable number for examination purposes. If

applicant elects group I, applicant is required to elect ONE independent and distinct sequence for prosecution. Examination will be restricted to only the one elected sequence. The search of no more than one selected sequences may include the complements of the selected sequence and where appropriate, may include subsequences within the selected sequence (i.e. oligomeric probes and/or primers). Applicants must elect a single sequence for examination. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996) which teaches

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, select to a restriction requirements pursuant to 35 U.S.C. 1121 and CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry to protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claim in light of *In re Ochiai, In re Brouwer* and 35 USC 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Claim 1 links the inventions of Groups I-XII. Claim 46 links the invention of Groups XIV-XVIII. Claim 51 links the invention of Groups XXI-XXII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are

advised that if any such claim depending from or including all the limitations of the allowable linking claims is presented in the continuation or divisional application, the claims of the continuation of divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See MPEP 804.01.

The searches required for the different groups are not coextensive. These inventions are distinct or the reasons given above and have acquired a separate status in the art Group I (435/455) versus Group II (514/2) versus Group III –IV, VI-VII and X-XII (435/375) versus Group V and XIX (530/350) versus Group VIII (435/334) versus Group IX (514/44) versus Group XIV (424/198.1) versus Group XV (424/143.1) versus Group XVI (435/69.1) versus Group XVII-XVIII (536/388.22) versus Group XX (536/22.1) versus Group XXI-XXII (435/7.1) as shown by their different classification and their recognized divergent subject matter. Furthermore, the searches required for the different groups are not coextensive, as a search for art pertaining to EDA1-II versus pertaining to DL or dl versus specific binding agents or EDA1-II antagonist or DL or dl antagonist. A search for art pertaining to an EDA1-II polypeptide versus a composition comprised of an EDA1-II polypeptide and an additional compound that increases hair follicle, sweat gland or tooth development. A search for art pertaining to compounds that increase development of hair follicle, tooth or sweat gland development versus a search for art pertaining to compounds that decrease development of hair follicle, tooth or sweat gland development. Therefore, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571) 272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571) 272-0278. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD
Examiner
Art Unit 1636

GERRY LEFFERS
PRIMARY EXAMINER

February 2, 2004